



RESEARCH PROTECTIONS UPDATE



News and Comments on the Protection of Human Subjects in Navy and Marine Corps Research

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DIRECTOR'S CORNER

The definition of partnership includes a formal arrangement between two or more parties to advance mutual interests. In today's busy society, it may be more appealing to eschew partnerships and work independently, however if partnerships are avoided, the immense benefits of working with others would be missed. These include diverse thoughts and experiences of others, and the ability to achieve something bigger than one could do on their own. When cooperation leads to accomplishment for both (or all) parties, it is a phenomenal feeling, as well as an efficient way to operate.

Partnership is a priority of both the Navy Surgeon General (SG) and the Chief of Naval Research (CNR). Rear Admiral Bruce Gillingham, Navy SG and the single point of accountability for Department of the Navy (DON) human research protections, has noted that people are the first of his four priorities, with partnerships serving as a principle that enables high value performance¹. Similarly, Rear Admiral Lorin Selby, CNR in command of the Office of Naval Research (ONR), has noted that collaboration and partnerships enable warfighters to tackle the challenges of 21st-century warfare².

As a program, DON HRPP benefits from the partnership between ONR Code 343 and Bureau of Medicine and Surgery (BUMED) Code M23 to ensure both line and medical research receive comprehensive oversight and monitoring, subject matter expertise, and a wider wealth of experience from which to draw. Partnerships are not always easy, but they are always worth the effort it takes to make them work.

In this issue, we also celebrate diversity through the observances of Days of Remembrance and Holocaust Remembrance Day, Asian American Pacific Islander Heritage Month, Pride Month, Juneteenth, Women's Equality Day, National Hispanic Heritage

Month, and National Disability Employment Awareness Month. Inclusive diversity coupled with partnership enables one to offer their talents and counteract their weaknesses, leading to better research and better protection of human subjects in research. We hope you will enjoy the theme of this issue, dedicated to partnerships in the human subjects research space.

-CDR Leedjia Svec

References

- 1) <https://www.dvidshub.net/news/359168/us-navy-surgeon-general-releases-guidance-fleet-focuses-people-platforms-performance-and-power>
- 2) <https://www.dvidshub.net/news/371205/welcome-aboard-rear-adm-selby-new-cnr-takes-helm-office-naval-research>

Commentary: Collaborative Human Research with the Department of the Navy

By Maria Rochelle Collantes

Investigators are engaged in research activities with human subjects in various ways, including independent collaborations with research teams, or with investigators from other institutions. Working in a collaborative manner with other investigators has its advantages, but investigators must

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Research Collaboration in the Navy *(continued from page 1)*

take precautions to address regulatory requirements for human subjects research (HSR).

Collaboration in research may be considered by investigators for a variety of reasons, including:

- To gain more expertise in the research activity;
- To obtain access to additional financial and logistic support, such as laboratory facilities, research personnel, or databases;
- To increase the number of research study participants;
- To create a network of researchers who can provide accessibility to a diverse pool of patients for clinical trials.

“While there is an intense focus on the pursuit of knowledge among these efforts, (particularly relevant to operational readiness and enhanced warfighter performance), there must also be equal attention given to address specific DoD and DON regulatory requirements for human subjects research activities.”

The Department of Navy (DON) has been involved with many collaborative research activities through the years. The DON has collaborated with other DON institutions, as well as other military services, Federal agencies, and non-Department of Defense (DoD) institutions. Examples of such activities include vaccine development, traumatic brain injury, mental health issues, cancer/infectious disease epidemiology and treatments, wound diagnostics and therapeutics.

While there is an intense focus on the pursuit of knowledge among these efforts, (particularly relevant to operational readiness and enhanced warfighter performance), there must also be equal attention given to address specific DoD and DON regulatory requirements for human subjects research activities.

The several requirements for research collaboration with the DoD are found in the DoD Instruction (DoDI) 3216.02, entitled, “Protection Of Human Subjects and Adherence to Ethical Standards in DoD-Conducted and -Supported Research, as well as in the Secretary of the Navy Instruction (SECNAVINST) 3900.39E CH-1 entitled “Human Research Protection Program.” Priority considerations include use of formal agreements to document the HSR regulatory requirements [such as Institutional Agreement for IRB Review (IAIR), Independent Investigator Agreement (IIA)] and other appropriate authorized arrangements [such as Data User Agreement (DUA)/Data Sharing Agreement

(DSA), Cooperative Research and Development Agreement (CRADA), Material Transfer Agreement (MTA), or Memorandum of Understanding (MOU)/Memorandum of Agreement (MOA), contracts, and grants]. Other considerations include verification that

collaborating institutions engaged in non-exempt human subjects research have federal assurances for the protection of human subjects, such as the Federalwide Assurance (FWA) from the U.S. Department of Health and Human Services (HHS), or a DoD Assurance (for DoD institutions). In addition, these human research collaborative activities may require IRB review, and in some cases, secondary administrative reviews by the DON. Secondary

reviews are specific to the research project, and may be completed in the form of either a Component Level Administrative Review (CLAR)¹, Human Research Protections Official (HRPO) review², or perhaps a security review³. These types of common secondary reviews are conducted to ensure that specific protections for DoD-affiliated personnel will be implemented during the conduct of the research activities.

Recommendations for Best Practices for Navy Human Research Collaboration

The following recommendations may provide more insight into best practices for compliance with regulatory requirements within the DON:

- Investigators may benefit by addressing regulatory requirements with their collaborators early on in the development of protocols, including reporting requirements for adverse events or non-compliance.
- Command-specific reference materials may assist investigators in navigating the requirements for conducting human subjects research with collaborators.
- Development of a plan for quality monitoring of collaborative human subjects research, including tracking of potential risks that may arise with research collaborations.
- IRB approval of research to satisfy all applicable regulatory requirements, including required collaborative agreements.

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Collaboration in the Navy *(continued from page 2)*

- Command awareness of all research activities, and communication with investigators and collaborators to encourage adherence to applicable DoD/DON requirements. Use of checklists or spreadsheets may facilitate such tracking and quality assurance.

Based on the experience of the DON through the years, there is a definite advantage to pursuing scientific research with a variety of collaborators and employing multiple strategies for collaboration. The importance of thorough oversight should also be given equal emphasis in order to minimize risks to subjects, the researchers and institutions as well as maximize the benefits from such collaborations.

References

- 1) DoDI 3216.02, Sections 3.5.b./3.6.a. and SECNAVINST 3900.39E CH-1, Enclosure (4), Section 3.i.; Enclosure (5), Section 1
- 2) DoDI 3216.02, Section 3.6.b. and SECNAVINST 3900.39E CH-1, Enclosure (3), Section 10; Enclosure (4), Sections 4b–4d; Enclosure (5), Section 1
- 3) DoDI 3216.02, Section 3.6.a.(2)



International Collaborations: Benefits, Challenges, and Strategies for Success

By Derek Englis

International collaboration in conducting research is becoming increasingly important. Matthews et al asserted, “Scientific research increasingly requires international collaboration among scientists.”¹ We have seen this in recent times as we have witnessed an urgent need for international collaboration with a raging global pandemic, COVID-19. In response to COVID-19 researchers came together to work towards developing COVID-19 vaccines, leading to a “global collaboration unlike any in history.”² International research collaborations, while having the potential to be beneficial, are not without challenges. In considering international research collaborations, we will briefly explore the benefits of research collaborations, the challenges associated with international collabora-

tions and research, and a model of international collaboration from Navy with the purpose highlighting strategies for overcoming these challenges.

There are inherent benefits associated with collaboration in conducting research, which can apply to international collaborations. Collaboration brings together a wider range of knowledge, expanding the combined expertise of the research team, which can assist in completing all research tasks.³ Collaboration allows for the transfer of knowledge (including tacit knowledge) between collaborating researchers.³ It brings about “a clash of ideas, a cross fertilization” which can lead to new ideas.³ Collaboration also provides “intellectual companionship” for collaborators, and allows researchers to broaden their network within the research community.³

These benefits apply to international collaborations, as well. Dusdal and Powell found that collaboration with researcher from differing countries can lead to more influential, more cited research.⁴ They also found that the knowledge and expertise of the persons from different countries enabled “in-depth global trend analysis and comparison of different national case studies.”⁴

There are challenges to international research collaboration, as well. Govere stated that, “When collaborative scientific projects expand across geographic boundaries, they introduce a new set of challenges, as culturally diverse individuals must share responsibilities.”⁵ Having research team members from different cultural backgrounds has an effect on communication.⁴ Cultural and language differences can complicate coordination efforts for research team members.

International Research Collaboration in the Navy

The Navy conducts infectious disease research in the United States and in areas of the world where certain infectious diseases, such as malaria, are more prevalent. In carrying out this research the Navy collaborates with local government agencies, local universities, and other local institutions. As the Navy has conducted this collaborative research in overseas locations and has worked to implement U.S. human subjects research regulations, it has faced several challenges. These challenges include, political issues that affect the willingness of overseas institutions to collaborate with the U.S. DoD. Another challenge has been limited resources available within the local country to carry out the study procedures and study laboratory

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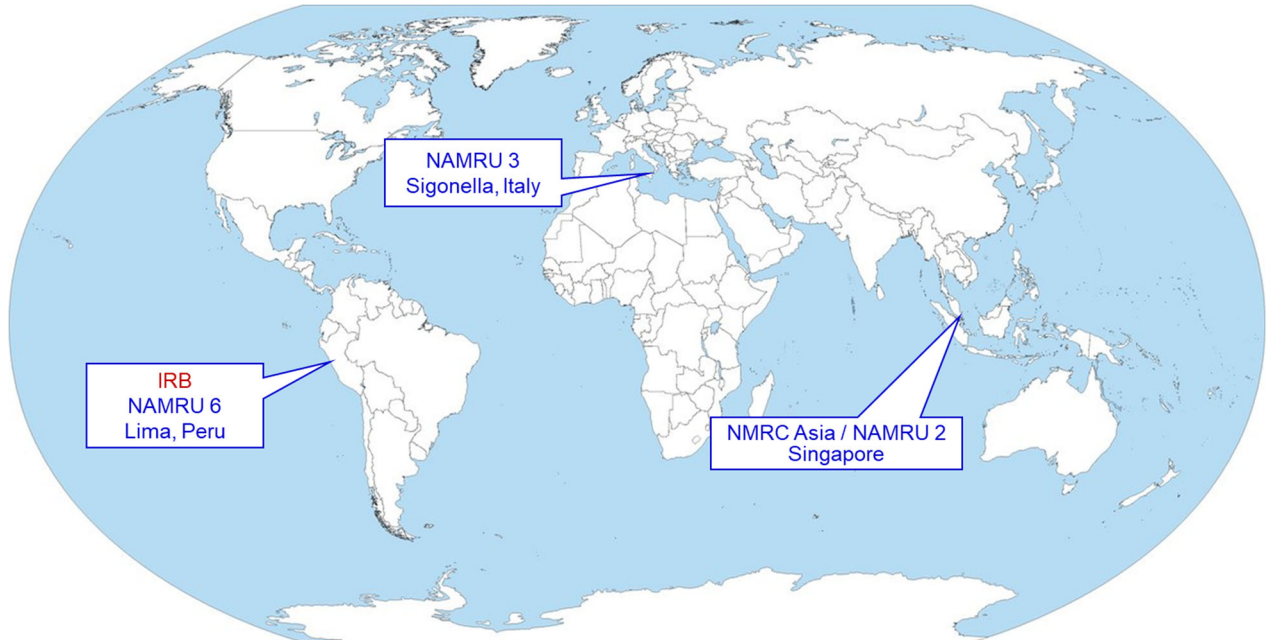
International Collaboration *(continued from page 3)*

tests.⁶ Lastly, cultural and language differences among collaborators create barriers to communication.⁶

As the Navy applies U.S. human subjects regulations to research conducted overseas it faces additional challenges.

Navy research must be conducted in accordance with U.S.-based human research protections principles which are founded in Western values.⁶ Differing values and worldviews may make the implementation of U.S.-based human research protections more difficult.⁶ For example, perceptions of the value of individualism or group cohesion may differ across cultures. These perceptions may influence how study processes (such as informed consent) are carried out.

In the face of these and other challenges the Navy has developed strategies that have enabled conducting successful international collaborative research, that is conducted in accordance with U.S. and host country human research protections. The overseas Navy research laboratories (NMRC-Asia/NAMRU-2 with headquarters in Singapore, NAMRU-3 with headquarters in Italy and detachments in Cairo and Ghana, and NAMRU-6 in Peru) collaborate with local ministry of health officials, local military medicine officials, and local non-governmental organizations, conducting infectious disease research that serves the local communities by building local diagnostic capabilities (equipment and training).⁶ These collaborations have allowed the Navy to better understand the targeted infectious diseases and treatments for such, benefiting the Navy and local populations. In addition, as a best practice, the Navy obtains host country ethics committee review board approval for the research it conducts overseas. Obtaining DoD IRB approval, and host country ethics committee board approval helps the Navy ensure that U.S. and local human subjects research requirements have been met. The



overseas research laboratories have also hired HRPP staff members that understand the local language, local culture, and the local political atmosphere. These staff members help facilitate communication with local collaborators.

These and other strategies have led to successful international collaborations for the Navy, have enabled the Navy to move forward with research on many infectious diseases, and move towards developing working vaccines/treatments. The Navy has helped build medical treatment capacity in some places, possibly benefiting local populations within countries where research is taking place, which has led to diplomacy through global health capacity.⁶ As Navy HRPP staff and researchers have worked with local collaborators they have also moved forward local human subjects research capabilities.⁶

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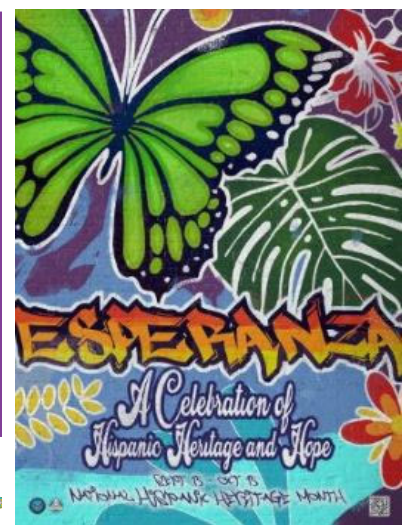
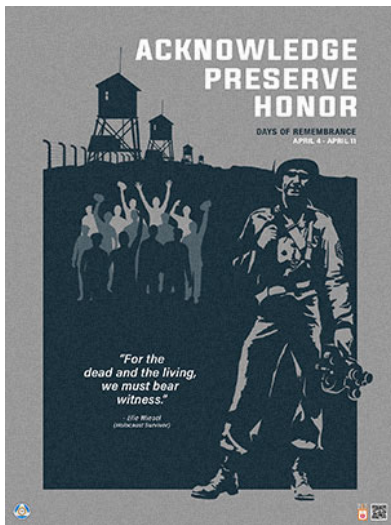
- 1) Matthews, Kirstin R. W., Yang, Erin, Lewis, Steven W., Vaidyanathan, Brandon R., Gorman, Monica. "International Scientific Collaborative Activities and Barriers to Them in Eight Societies." *Accountability in Research*. (2020) 27:8, 477-495.
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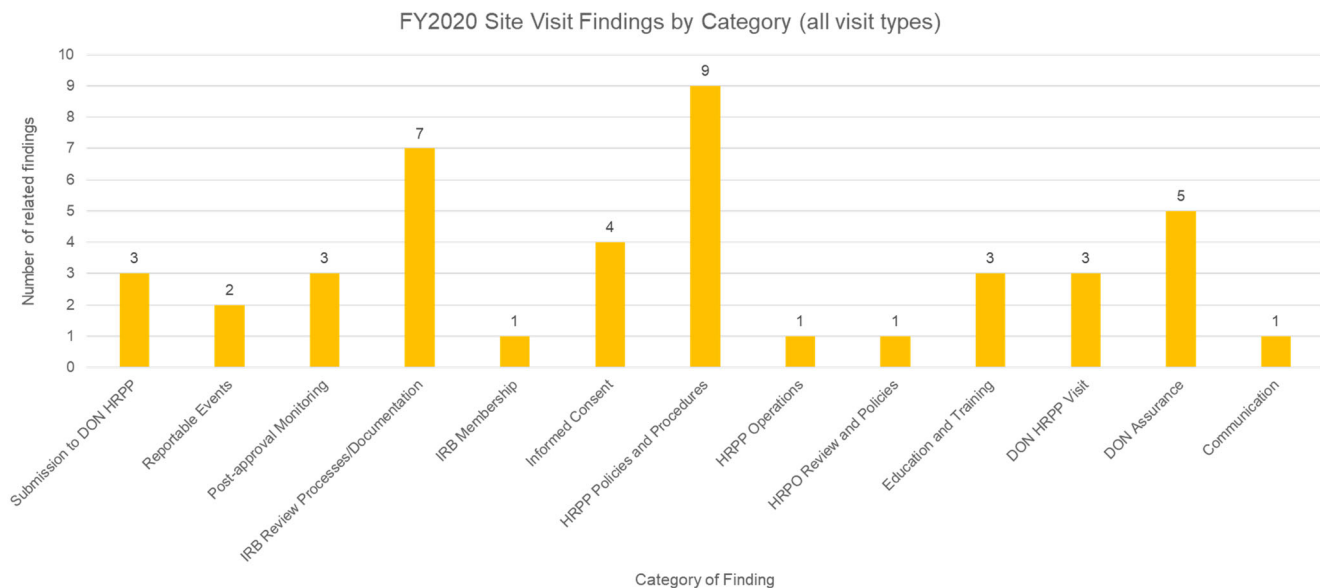
Special Observances April to October 2021

1. Holocaust Days of Remembrance 4 – 11 April 2021; Holocaust Remembrance Day 8 April 2021
2. Asian American Pacific Islander Heritage Month – May 2021
3. Pride Month – June 2021
4. Juneteenth – 19 June 2021
5. Women's Equality Day – 26 August 2021
6. National Hispanic Heritage Month – 15 September 2021 to 15 October 2021
7. National Disability Employment Awareness Month – October 2021

For more ways to celebrate diversity, please see observance materials provided by the Defense Equal Opportunity Management Institute at <https://www.defenseculture.mil/>



DON HRPP Quality Assurance Activities: FY2020 Site Visit Findings Analysis



FY2020 resulted in fewer DON HRPP visits to assured institutions than expected due to the global COVID-19 pandemic. All visits during the latter half of 2020 were completed off-site/virtually. DON HRPP staff conducted two (2) on-site inspections and eight (8) other visits (off-site/virtual) in FY2020. The chart above summarizes the categories of findings from all FY2020 visits. Comparing visit findings of FY2020 to those of FY2019, HRPP Policies and Procedures and IRB Review Process/Documentation categories remain as two (2) of the most frequent findings. This is expected given recent changes to the Common Rule and DoDI 3216.02.

WELCOME!!

Fair Winds and Following Seas

New Members of the Office of Naval Research's (ONR) DON HRPP Team

DON HRPP welcomes new Human Research Compliance Specialist, Kathleen Prendergast, to ONR's Research Protection Division. Ms. Prendergast joined ONR in April 2021. Prior to joining ONR, Ms. Prendergast worked at AbbVie, a pharmaceutical company in North Chicago, Illinois. She held prior jobs in clinical research at various academic medical centers in Chicago. She holds a Bachelor's of Arts Degree in English and Psychology, and a Master's of Science Degree in Clinical Research and Regulatory Administration. While at AbbVie, she performed full-time clinical trial budget development for pharmaceutical products in all stages of AbbVie's pipeline. In addition to budget development, she worked with study teams to understand the legalities of clinical trial budgeting, as well as the negotiation process, ensuring compliance with all applicable state and federal laws.

The following individuals have detached from the DON HRPP. We are very appreciative to each of them for all their hard work and dedication during the time they worked with the DON HRPP team.

- Ms. Patricia Yasenchak - Human Research Protection Specialist
- Ms. Chidima Ioanou - Training and Education Specialist
- Ms. Kathleen Osei - Human Research Protection Specialist
- Ms. Heather Hermann - Human Research Protection Specialist
- Ms. Ashleigh Gill - Human Research Protection Specialist

Thank you!!!! We wish them all the best in their future endeavors.

International Collaboration *(continued from page 4)*

- 3) Katz, J. Sylvan, Martin, Ben R. "What is Research Collaboration?", *Research Policy*, (1997) 26/1: 1–18.
- 4) Dusdal, Jennifer, Powell, Justin J. W. "Benefits, Motivations, and Challenges of International Collaborative Research: A Sociology of Science Case Study." *Science and Public Policy*. (2021) 48:2, Pages 235–245.
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DON HRPP News!!

- The Juneteenth Holiday was officially observed by DON HRPP for the first time on 18 June 2021!
- Public Responsibility in Medicine and Research (PRIM&R) Advancing Ethical Research (AER) Virtual Conference 2021 (17-19 November 2021)
 - The BUMED conference package to attend PRIM&R has been approved.
 - Conference registration is open. Visit <https://www.eventscribe.net/2021/AER-SBER21/>

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Have a "Good News" story or picture from your Research Protection Program? Don't keep it to yourself! Why not share it with the DON Research Protection community? We're looking for material to publish in the *Research Protections Update* newsletter. Send your research news, success stories, tips, pictures, lessons learned, or other material related to the ethical conduct of human research to